

Commission's Rules of Practice and Procedure, the initial decision of the Administrative Law Judge shall be issued by April 12, 1995 and the final decision of the Commission shall be issued by August 10, 1995.

Joseph C. Polking,
Secretary.

[FR Doc. 94-9179 Filed 4-14-94; 8:45 am]

BILLING CODE 6730-01-M

FEDERAL RESERVE SYSTEM

First Financial Partners Fund I, L.P., et al.; Formations of; Acquisitions by; and Mergers of Bank Holding Companies

The companies listed in this notice have applied for the Board's approval under section 3 of the Bank Holding Company Act (12 U.S.C. 1842) and § 225.14 of the Board's Regulation Y (12 CFR 225.14) to become a bank holding company or to acquire a bank or bank holding company. The factors that are considered in acting on the applications are set forth in section 3(c) of the Act (12 U.S.C. 1842(c)).

Each application is available for immediate inspection at the Federal Reserve Bank indicated. Once the application has been accepted for processing, it will also be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing to the Reserve Bank or to the offices of the Board of Governors. Any comment on an application that requests a hearing must include a statement of why a written presentation would not suffice in lieu of a hearing, identifying specifically any questions of fact that are in dispute and summarizing the evidence that would be presented at a hearing.

Unless otherwise noted, comments regarding each of these applications must be received not later than May 6, 1994.

A. Federal Reserve Bank of Richmond (Lloyd W. Bostian, Jr., Senior Vice President) 701 East Byrd Street, Richmond, Virginia 23261:

1. *First Financial Partners Fund I, L.P.*, New York, New York; to become a bank holding company by acquiring 62.9 percent of the voting shares of Treasury Bank, Ltd., Washington, D.C.

B. Federal Reserve Bank of St. Louis (Randall C. Sumner, Vice President) 411 Locust Street, St. Louis, Missouri 63166:

1. *Banterra Corp.*, Eldorado, Illinois; to acquire 100 percent of the voting shares of Hopkins Bancorp, Inc., Wickliffe, Kentucky, and thereby

indirectly acquire Citizens State Bank of Wickliffe, Wickliffe, Kentucky.

C. Federal Reserve Bank of Minneapolis (James M. Lyon, Vice President) 250 Marquette Avenue, Minneapolis, Minnesota 55480:

1. *Pipestone Bancshares, Inc.*, Pipestone, Minnesota; to merge with Upper Midwest Financial Corporation, Garretson, South Dakota, and thereby indirectly acquire First National Bank in Garretson, Garretson, South Dakota.

D. Federal Reserve Bank of Kansas City (John E. Yorke, Senior Vice President) 925 Grand Avenue, Kansas City, Missouri 64198:

1. *Community Bancshares of Marysville, Inc.*, Marysville, Kansas; to become a bank holding company by acquiring 100 percent of the voting shares of Citizens Bancshares of Marysville, Inc., Marysville, Kansas; The Citizens State Bank of Marysville, Marysville, Kansas; Citizens Bancshares of Waterville, Inc., Waterville, Kansas; and The Citizens State Bank of Waterville, Waterville, Kansas.

Board of Governors of the Federal Reserve System, April 11, 1994.

Jennifer J. Johnson,

Associate Secretary of the Board.

[FR Doc. 94-9110 Filed 4-14-94; 8:45 am]

BILLING CODE 6210-01-F

Terry P. Gilmore; Change in Bank Control Notices; Acquisitions of Shares of Banks or Bank Holding Companies; Correction

This notice corrects a notice (FR Doc. 94-8183) published on page 16210 of the issue for Wednesday, April 6, 1994.

Under the Federal Reserve Bank of Dallas heading, the entry for Terry P. Gilmore, is revised to read as follows:

1. *Terry P. Gilmore*, San Marcos, Texas; to acquire 24.52 percent, for a total of 49.04 percent, of the voting shares of S.B.T. Bancshares, Inc., San Marcos, Texas, and thereby indirectly acquire State Bank and Trust Company, San Marcos, Texas.

Comments on this application must be received by April 19, 1994.

Board of Governors of the Federal Reserve System, April 11, 1994.

Jennifer J. Johnson,

Associate Secretary of the Board.

[FR Doc. 94-9111 Filed 4-14-94; 8:45 am]

BILLING CODE 6210-01-F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 93E-0099]

Determination of Regulatory Review Period for Purposes of Patent Extension; Mycobutin™

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for Mycobutin™ and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Commissioner of Patents and Trademarks, Department of Commerce, for the extension of a patent which claims that human drug product.

ADDRESSES: Written comments and petitions should be directed to the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Brian J. Malkin, Office of Health Affairs (HFY-20), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 801-443-1382.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98-417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100-670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: a testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the

Commissioner of Patents and Trademarks may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA recently approved for marketing the human drug product Mycobutin™ (rifabutin). Mycobutin™ is indicated for the prevention of disseminated *Mycobacterium avium* complex (MAC) disease in patients with advanced human immunodeficiency virus (HIV) infection. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for Mycobutin™ (U.S. Patent No. 4,219,478) from Adria Laboratories, and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. FDA, in a letter dated June 7, 1993, advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of Mycobutin™ represented the first commercial marketing or use of the product. Shortly thereafter, the Patent and Trademark Office requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for Mycobutin™ is 2,831 days. Of this time, 2,124 days occurred during the testing phase of the regulatory review period, while 707 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act became effective.* March 23, 1986. The applicant claims April 18, 1986, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was March 23, 1986, which was 30 days after FDA receipt of the IND.

2. *The date the application was initially submitted with respect to the human drug product under section 507 of the Federal Food, Drug, and Cosmetic Act.* January 17, 1992. The applicant claims January 16, 1992, as the date the new drug application (NDA) for Mycobutin™ (NDA 50-689) was initially submitted. However, FDA records indicate that NDA 50-689 was initially submitted on January 17, 1992.

3. *The date the application was approved.* December 23, 1992. FDA has verified the applicant's claim that NDA

50-689 was approved on December 23, 1992.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 1,392 days of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may, on or before June 14, 1994, submit to the Dockets Management Branch (address above) written comments and ask for a redetermination. Furthermore, any interested person may petition FDA, on or before October 12, 1994, for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41-42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Comments and petitions should be submitted to the Dockets Management Branch (address above) in three copies (except that individuals may submit single copies) and identified with the docket number found in brackets in the heading of this document. Comments and petitions may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 5, 1994.

Stuart L. Nightingale,
Associate Commissioner for Health Affairs.
[FR Doc. 94-9099 Filed 4-14-94; 8:45 am]
BILLING CODE 4160-01-F

Advisory Committees; Notice of Meetings

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: This notice announces forthcoming meetings of public advisory committees of the Food and Drug Administration (FDA). This notice also summarizes the procedures for the meetings and methods by which interested persons may participate in open public hearings before FDA's advisory committees.

FDA is in the process of implementing a voice mail telephone system which will allow the public to obtain information regarding advisory committee meetings. The public will be

able to access the use of this information system by calling 1-800-741-8138. The project implementation date is May 1, 1994.

MEETINGS: The following advisory committee meetings are announced:

Circulatory System Devices Panel of the Medical Devices Advisory Committee

Date, time, and place. May 2, 1994, 8:30 a.m., and May 3, 1994, 8 a.m., Holiday Inn—Bethesda, Versailles Ballroom I, 8120 Wisconsin Ave., Bethesda, MD. A limited number of overnight accommodations have been reserved at the Holiday Inn—Bethesda. Attendees requiring overnight accommodations must contact the hotel at 301-652-2000 and reference the FDA Panel meeting block. Reservations will be confirmed at the group rate based on availability.

Type of meeting and contact person. Open public hearing, May 2, 1994, 8:30 a.m. to 9:30 a.m., unless public participation does not last that long; open committee discussion, 9:30 a.m. to 3 p.m.; closed committee deliberations, 3 p.m. to 5 p.m.; open public hearing, May 3, 1994, 8 a.m. to 9:30 a.m., unless public participation does not last that long; open committee discussion, 9:30 a.m. to 1 p.m.; Ramiah Subramanian, Center for Devices and Radiological Health (HFZ-450), Food and Drug Administration, 1390 Piccard Dr., Rockville, MD 20850, 301-594-2623.

General function of the committee. The committee reviews and evaluates data on the safety and effectiveness of marketed and investigational devices and makes recommendations for their regulation.

Agenda—Open public hearing. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Those desiring to make formal presentations should notify the contact person before April 27, 1994, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time required to make their comments.

Open committee discussion. The committee will discuss a coronary interventional device and a dysrhythmia treatment device.

Closed committee deliberations. The committee may discuss trade secret and/or confidential commercial information. This portion of the meeting will be closed to permit discussion of this information (5 U.S.C. 552b(c)(4)).